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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,877	03/30/2001	Paul F. Coleman	6794.US.01	5339

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EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,877	COLEMAN ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *25-27* is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 25-27 been renumbered 24-26.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 5 and 6, drawn to an isolated nucleotide sequence having at least 70% sequence identity to SEQ ID NO: 1, classified in class 536, subclass 23.72.

II. Claims 2, 5 and 6, drawn to an isolated nucleotide sequence that encodes a mutant hepatitis B surface antigen, classified in class 536, subclass 23.72.

III. Claims 3, 11, 16 and 23, drawn to a purified polypeptide, classified in class 530, subclass 350 and class 424, subclass 227.1.

IV. Claim 4, drawn to a polypeptide comprising at least 70% identity to SEQ ID NO: 2, classified in class 530, subclass 350.

V. Claim 7, drawn to a method of producing a polypeptide by expression in a host cell, classified in class 435, subclass 70.1.

VI. Claims 8 and 15, drawn to an antibody that binds to HBsAg, classified in class 530, subclass 387.1.

VII. Claims 9 and 11, drawn to an isolated mutant HSV and an immunogenic composition, classified in class 424, subclass 227.1.

VIII. Claim 10, drawn to a tissue culture-infected cell, classified in class 435, subclass 325.

IX. Claims 12-14, drawn to a polynucleotide probe, classified in class 536, subclass 24.3.

X. Claim 17, drawn to a method of detecting HBV nucleic acids with a probe, classified in class 435, subclasses 5 and 6.

XI. Claims 18-21, drawn to a method of detecting HBV antibodies, classified in class 435, subclasses 5 and 7.1.

XII. Claims 22, 25 and 26, drawn to an isolated nucleic acid having 70% identity to SEQ ID NO: 4, classified in class 536, subclass 23.72.

XIII. Claim 24, drawn to a polypeptide having at least 70% identity to SEQ ID NO: 5, classified in class 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally distinct nucleic acid sequences. Each sequence is also functionally distinct because each expresses a different product. Therefore, each of the nucleic acid sequences of groups I, II and XII have different functions and produce different effects.

Inventions III, IV and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to polypeptides comprising a unique sequence of amino acid residues. The polypeptides of groups III, IV and XIII have different functions and activities because of the distinct structural characteristics. Therefore, each of the polypeptides have different modes of operation, different functions and different effects.

Inventions I, II, XII and III, IV, XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, I, II, XII are composed of nucleic acid residues while the polypeptides of groups III, IV, XIII are composed of amino acids. None of the groups require the other for existence because each molecule can be made synthetically. Therefore, each of the groups are patentably distinct because each has different modes of operation, different functions and different effects.

Inventions I, II, XII, III, IV, XIII and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are structurally and functionally distinct. The polynucleotides of groups I, II and XII an the polypeptides of groups III, IV and XIII do not have the same functional capabilities the antibody of group VI. Each of the inventions differ in their

physical properties such as chemical structure, primary sequence, molecular weight and are novel and unobvious over each other.

Inventions VII, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the mutant virus of group VII, the tissue culture-infected cell of group VIII and the polynucleotide probe of group IX do not have any structural or functional similarities with one another. Each group is separately classified and has separate fields of search.

Inventions I, II, XII, III, IV, XIII, VI and VII, VIII, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Polypeptides, polynucleotides, antibodies, mutant herpesviruses, tissue culture-infected cells, and probes possess unique structural features and functional characteristics. The nucleic acid probes of group IX do not possess the same nucleic acid sequence of group I, II, XII and are therefore, functionally distinct from one another.

Inventions V and III, IV and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method can be used to make any of the patentably distinct polypeptides of groups III, IV and XIII. Alternatively, the polypeptides of groups III, IV and XIII can be made synthetically.

Inventions X and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of detecting HBV nucleic acids can be practiced in a materially different method, such as PCR amplifying a sample suspected of containing HBV nucleic acids and electrophoretically detecting the presence of the amplified product.

Inventions III, VI and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of detecting HBV antibodies can be practiced with materially different products, i.e. the polypeptide of group III or the antibody of group IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, a search for one group is not coextensive with a search for another group. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
June 28, 2003